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Review

Does vacuum delivery carry a higher risk of shoulder dystocia? Review and meta-analysis of the literature

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ABSTRACT

Introduction: Vacuum extractor has been increasingly used over the last decades and is acknowledged as a risk factor for shoulder dystocia (SD). In this meta-analysis we assess the actual risk of SD following a vacuum delivery compared to spontaneous vaginal delivery (SVD) and forceps.
Materials and methods: Systematic literature search (English literature only) on MEDLINE, EMBASE, ScienceDirect, the Cochrane library and ClinicalTrials.gov conducted up to May 2015. Key search terms included: Operative/Vacuum/Forceps delivery [Mesh] and shoulder dystocia and subheadings. 2 stage-process study selection. We included only studies where data concerning the occurrence of SD following operative vaginal delivery were reported as adjusted odds ratio (AOR) and no significant difference in confounding factors for SD was recorded. Included trials clustered according to the delivery mode (1) vacuum vs. SVD, (2) forceps vs. vacuum. Methodological quality of each study evaluated with the Newcastle–Ottawa System (NOS).
Results: 87 potentially relevant papers. After applying inclusion and exclusion criteria only 7 were selected for the meta-analysis. Vacuum delivery appeared associated with a higher risk of SD than SVD in both fixed and random model (OR 2.87 and 2.98 respectively). No difference in the rate of SD was found between vacuum and forceps ($p > 0.05$).
Conclusion: Vacuum extractor carries an increased risk of SD compared with spontaneous vaginal delivery whereas the occurrence of SD does not seem to vary following vacuum or forceps.

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Introduction

According to the Royal College of Obstetricians and Gynecologists guidelines shoulder dystocia (SD) is defined as "a vaginal cephalic delivery that requires additional obstetric manoeuvres to deliver the fetus after the head has been delivered and a gentle

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traction has failed" [1]. SD has been described as an unpreventable and unpredictable obstetric emergency which may carry an increased risk of severe complications including maternal haemorrhage, fourth-degree laceration, fracture of the clavicle or humerus, temporary or permanent brachial plexus injury, hypoxic ischemic encephalopathy and neonatal death [2,3].

Such a complication is relatively uncommon in the general population with an overall incidence ranging from 0.2 to 3% [4]. The occurrence of SD is consistently reported to be higher among large for gestational age newborns, being a progressive increase quoted as birtweight exceeds 4000 g [5,6].

Among the risk factors for SD, the instrumental vaginal delivery by vacuum extractor has been widely acknowledged in previous studies [7,8].

However controversy still exists regarding the genuine contribution of vacuum delivery (VD) to SD [9]. This association has been evaluated indeed only in retrospective studies where more importantly the impact of VD has not been analyzed independently from additional confounding factors [10,11,12,13]. In the only available Randomized Controlled Trial (RCT) no significant difference was found in the occurrence of SD following VD and forceps [14,15]. On the basis of this uncertainty we designed this meta-analysis with the aim of assessing the available literature regarding the actual risk of SD following a VD compared to SVD and forceps.

Sources

A systematic literature search up to December 2015 was conducted on the following electronic databases MEDLINE, EMBASE, ScienceDirect, the Cochrane library and ClinicalTrials.gov.

All the studies which included data regarding the incidence of SD in SVDs and operative vaginal deliveries by vacuum and forceps were collected and analyzed.

The key search terms included: Operative/Vacuum/Forceps delivery [Mesh] and shoulder dystocia, adding the subsequent subheadings: labor complication OR dysfunctional labor OR brachial palsy OR type of delivery OR neonatal adverse events.

After screening of titles, abstracts and full texts, the selection of included studies was based on the availability of information regarding SD, mode of delivery (SVD or operative delivery) and device used for operative delivery (vacuum or forceps).

Study selection

The studies were selected in a 2-stage process. Titles and abstracts from electronic searches were scrutinized by one reviewer (AD). Full manuscripts and their citations list were re-analyzed to retrieve missing articles and include those which fulfilled the inclusion criteria.

We considered eligible all the trials reporting data on the occurrence of SD following operative vaginal delivery, either with vacuum extractor or forceps, in comparison with SVD. Among the eligible studies we included only those where the odds ratio (OR) was adjusted for confounding factors (AOR) after multivariate regression analysis and those where there was no significant difference in terms of the reported confounding factors in order to minimize the risk of bias in the interpretation of the results.

The assessed confounding factors were classified as follows:

- Maternal and demographic features: maternal diabetes (DM) and gestational diabetes (GDM), parity, ethnicity, obesity;
- Labor and delivery features and outcomes: birthweight, labor induction, length of the first and the second stage, "prolonged labor", epidural analgesia, head position and station, indication for operative delivery.

We did not distinguish on the basis of the cup used in the operative delivery by vacuum nor of the type of forceps and included both direct and rotational procedures.

We also excluded those studies where no data was available for analysis according to original allocation or those whose data format was not suitable for analysis.

In the eligible studies two Authors (AD, TG) extracted the data using the agreed upon form: we extracted AOR if available; if not, we extracted the raw numbers after assessment of the confounding factors for SD. The data were entered into the pre-installed Data Sheet form of free Excel software extension for meta-analysis and checked for accuracy by a third reviewer (GP).

Regarding the outcome SD we clustered the included trials according to the following delivery mode:

- Ventouse vs. SVD;
- Forceps vs. ventouse.

The methodological quality of each study was evaluated with the Newcastle–Ottawa Scale scoring system (NOS) [16]. The risk of bias in selection, comparability and outcomes for both branches are shown in Tables 1 and 2.

Endpoints

The primary endpoint was to compare the incidence of SD following operative delivery by vacuum extractor vs. SVD. The secondary endpoint was to compare the incidence of SD following operative delivery by forceps vs. vacuum.

Statistical analysis

The meta-analyses was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [17] using the statistical system "R" v. 3.2.0 (R Development Core Team (2015). R: a language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. ISBN 3-900051-07-0, URL http://www.R-project.org/) together with the R packages "meta v. 4.3-0 (2015)", "meta v. 2.16 (2015)" and "metafor v. 1.9-7(2015)".

The software considers both fixed effect and random effects models. Mantel–Haenszel method is the default procedure to calculate the fixed effect estimate (inverse variance weighting and the Peto method are also available). Heterogeneity has been evaluated through the Cochrane Q statistics and the τ^2,H^2 and I^2 indices. DerSimonian–Laird is the default method to estimate the random effects model [18].

The data analyzed in our study were all dichotomous and the results were presented as odds ratio (OR). A summary OR was then calculated using both fixed and random effects model from OR for the end point using Mantel–Haenszel methods. A forest plot was also produced. The results were considered significant when $p < 0.05$.

Table 1
Newcastle–Ottawa Scale (NOS) vacuum vs. SVD.

Study	Selection[a]	Comparability[b]	Outcome[c]
Sheiner et al. [9]	★★★★	★★	★★★
Cheng et al. [26]	★★★★	☆★	★★★
Revicky et al. [26]	★★★★	☆★	★★★
Overland et al. [3]	★★★★	☆★	★★★

[a] Range 0–4.
[b] Range 0–2.
[c] Range 0–3.